K032765

ORIGINAL, TRADITIONAL 510(K) NOTIFICATION
PERMOBIL POWERED WHEELCHAIR: **STREET**

JAN 2 0 2004

Attachment 12

510(k) Summary

Submitter Permobil AB
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Contact Person: Bengt Persson
e-mail address: bengt.persson@permobil.se

Date Prepared: September 1, 2003

Device name: STREET

Classification Name:
Powered wheelchair

Predicate Devices:
Quantum Blast (K011993) manufactured by Pride Mobility .

Intended use:

The intended use of the STREET powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Description of device:

Street Powered Wheelchair is battery powered, rear wheel motor driven and is controlled by the PG power wheelchair PM100Amp controller.
The user interface is a joystick.
The Street is powered by two 12VDC 73Ah, Group 24 batteries, approximate driving range on fully charged batteries is up to 35 km (22 miles), depending on use and the terrain the chair is driven on.
The chair frame is of welded steel construction and includes two rear drive wheels with drive units (motor, gear, brake), batteries and front pivoting casters.
Depending on users needs, the joystick motor control is mounted to the left or right armrest.
When the user activates the joystick, the controller receives a signal to release the brakes.
With the brakes released, the chair is allowed to move in the direction the joystick is actuated.
When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user stop by letting go of the joystick.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2004

Mr. Bengt Persson
Director, Quality and Environment
Permobil AB
Box 120
Årvältsvägen 10
S-861 23 Timrå
Sweden

Re: K032765
Trade/Device Name: STREET
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: December 2, 2003
Received: December 2, 2003

Dear Mr. Persson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 13

Indication for Use Statement

Substantial Equivalence

The product, which is substantially equivalent to this device, is Pride Mobility's Quantum Blast Rear Wheel Drive Power Wheelchair (K011993 July 13, 2000).

Safety and effectiveness

The STREET has in substantially the same intended use and similar technological characteristics as the Quantum Blast.
Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in technological characteristics do not raise any new questions of safety or effectiveness. Thus, the STREET device is substantially equivalent to the predicate device.

Indication for Use

The intended use is to provide indoor and outdoor mobility to persons restricted to a sitting position.

510(k) number

Not assigned at the writing of this submission

Device name

STREET

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR 801.109) ☐ or **Over the counter use** ☑

f Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

K032765

(Division Sign-Off)
Division of General Restorative Devices

510(k) number ______________